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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,141	12/14/2001	Jeanette McCarthy	MMI-002	6651

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,141	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-150* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-150* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method for identifying a subject as a candidate for a particular clinical course of therapy to treat a vascular disease or disorder, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE the below summarized specie elections and additional subspecie elections are also required.

II. Claims 10-16, 55-59, and 65-78, drawn to a method for diagnosis and for identifying a subject who is a candidate for further diagnostic evaluation for a vascular disease or disorder, classified in class 706, subclass 21 and class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then THREE of the below summarized specie elections are also required.

III. Claims 17-25 and 63-64, drawn to a method of treating and for selecting a clinical course of therapy to treat a subject who is at risk for developing a vascular disease or disorder, classified in class 435, subclass 6 and class 514, subclass 1. If this Group is elected then the below summarized sequence elections are also required. Also, if this Group is elected then ONE of the below summarized specie elections and additional subspecie elections are also required.

IV. Claims 26-29, drawn to a method for determining if a subject will benefit from a stent implantation, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required.

V. Claims 30-34, drawn to a method for determining if a subject will benefit from a vascular imaging procedure, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.

VI. Claims 35-39, drawn to a method for determining if a subject will benefit from a surgical procedure, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is also required.

VII. Claims 40-44, drawn to a method for selecting an effective vascular imaging device as a diagnostic tool, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.

VIII. Claims 45-54, drawn to a computer readable medium, electronic system, and network system used in performing a method of predisposition determination to a vascular disease or disorder, classified in class 211, subclass 41.12; class 702, subclass 19; and class 706, subclass 21. If this Group is elected then the below summarized sequence election is also required.

IX. Claims 60-62, drawn to a method for selecting the appropriate drug for a vascular disease or disorder, classified in class 702, subclass 27. If this Group is elected then the below summarized sequence election is also required.

X. Claims 79-83, drawn to a nucleic acid and kit comprising an allelic variant of a polymorphic region, classified in class 536, subclass 23.1. If this Group is elected then the below summarized sequence election is also required.

XI. Claims 84-104, drawn to a method and medical information system of determining identity of one or more allelic variants of a polymorphic region, classified in class 706, subclass 21 and class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is also required.

XII. Claims 105-109, drawn to a computerized method of providing medical advice, classified in class 706, subclass 46. If this Group is elected then the below summarized sequence election is also required.

XIII. Claims 110-120, drawn to a method for self-assessing risk for a vascular disease, classified in class 706, subclass 45. If this Group is elected then the below summarized sequence election is also required.

XIV. Claims 121-122, drawn to a method for health care provider to generate a personal health assessment report, classified in class 706, subclass 45. If this Group is elected then the below summarized sequence election is also required.

XV. Claims 123-150, drawn to a method for assessing the health of an individual using digital molecular and digital health data in its assessment determination, classified in class 706,

subclass 47. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie elections is also required.

Sequence Election Requirement for Groups I-XV:

The claims in this invention read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences. For nucleotide sequences, the Applicants must elect a single nucleic acid sequence with one nucleotide position therein, or alternatively, a specific set of sequence and/or nucleotide positions within each elected sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Specie Election Requirements for Groups I-III, V-VII, XI, and XV:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie Election Requirement for Groups I and III:

Specie A: surgical procedure with a medical device implantation

Specie B: surgical procedure without a medical device implantation

Specie C: medical device usage without surgery

First Subspecie Election Requirement for Groups I or III if Species A or C is chosen:

Subspecie AA: a medical device which is a defibrillator

Subspecie BB: a medical device which is a stent

Subspecie CC: a medical device which is a device used in coronary revascularization

Subspecie DD: a medical device which is a pacemaker

Subspecie EE: a medical device which is unspecified above

(If Subspecie EE is elected, please specify which type of medical device)

Subspecie FF: a medical device which is a combination of medical devices

(If Subspecie FF is elected, please specify which medical devices)

Second Subspecie Election Requirement for Groups I and III if Species A or C is chosen:

Subspecie GG: a medical device used without a modulator

Subspecie HH: a medical device used in combination with a ITGB3 modulator

Subspecie II: a medical device used in combination with a VWF modulator

Subspecie JJ: a medical device used in combination with EDNRB modulators

Subspecie KK: a medical device used in combination with F2 modulators

Subspecie LL: a medical device used in combination with SELP modulators

Subspecie MM: a medical device used in combination with THBS1 modulators

Subspecie NN: a medical device used in combination with THBS2 modulators

Subspecie OO: a medical device used in combination of the above modulators

(If Subspecie OO is elected, please specify which combination of modulators are used)

Third Subspecie Election Requirement for Groups I and III if Species A or B is chosen:

Subspecie PP: a surgical procedure which is percutaneous transluminal coronary angioplasty

Subspecie QQ: a surgical procedure which is laser angioplasty

Subspecie RR: a surgical procedure which is a stent implantation

Subspecie SS: a surgical procedure which is coronary bypass grafting

Subspecie TT: a surgical procedure which is a defibrillator implantation

Subspecie UU: a surgical procedure which is a pacemaker implantation

Subspecie VV: a surgical procedure which is unspecified above

(If Subspecie VV is elected, please specify which type of surgical procedure)

Subspecie WW: a surgical procedure which is combination of the above surgical procedures

(If Subspecie WW is elected, please specify which procedures)

For Group VI:

Specie D: a surgical procedure which is percutaneous transluminal coronary angioplasty

Specie E: a surgical procedure which is laser angioplasty

Specie F: a surgical procedure which is a stent implantation

Specie G: a surgical procedure which is coronary bypass grafting

Specie H: a surgical procedure which is a defibrillator implantation

Specie I: a surgical procedure which is a pacemaker implantation

Specie J: a surgical procedure which is unspecified above

(If Specie J is elected, please specify which type of surgical procedure)

Specie K: a surgical procedure which is combination of the above surgical procedures

(If Specie K is elected, please specify which procedures)

For Groups II, V, and VII:

Specie L: a vascular imaging device which is angiography

Specie M: a vascular imaging device which is cardiac ultrasound

Specie N: a vascular imaging device which is coronary angiogram

Specie O: a vascular imaging device which is magnetic resonance imagery

Specie P: a vascular imaging device which is nuclear imaging

Specie Q: a vascular imaging device which is CT scan

Specie R: a vascular imaging device which is myocardial perfusion imagery

Specie S: a vascular imaging device which is electrocardiogram

Specie T: a vascular imaging device which is unspecified above

(if Specie T is elected, please specify which type of vascular imaging device)

Specie U: a vascular imaging device which is a combination of vascular imaging devices

(If Specie U is elected, please specify which vascular imaging devices)

For Group II:

Specie V: a vascular disease which is atherosclerosis

Specie W: a vascular disease which is coronary artery disease

Specie X: a vascular disease which is myocardial infarction

Specie Y: a vascular disease which is ischemia

Specie Z: a vascular disease which is stroke

Specie AA: a vascular disease which is peripheral vascular diseases

Specie BB: a vascular disease which is venous thromoembolism

Specie CC: a vascular disease which is pulmonary embolism

Specie DD: a vascular disease which is unspecified above

(If Specie DD is elected, please specify which type of vascular disease)

For Group XI:

Specie EE: allelic variant identification process using restriction enzyme site analysis

Specie FF: allelic variant identification process using single-stranded conformation polymorphism

Specie GG: allelic variant identification process using allele specific hybridization

Specie HH: allelic variant identification process using primer specific extension

Specie II: allelic variant identification process using oligonucleotide ligation assay

Specie JJ: allelic variant identification process using an unspecified process above

(If Specie JJ is elected, please specify which type of allelic variant identification process)

For Group XV:

Specie KK: a method based on biological information collected from one time point

Specie LL: a method based on biological information collected from two different time points

For Group II:

Specie MM: a method of diagnosis of increased likelihood of disease

Specie NN: a method of diagnosis of decreased likelihood of disease

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie or subspecie for the appropriate specie and subspecie elections for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. This distinctness or independence of surgery and/or medical device (Groups I and III) and various medical devices (Groups I and III), various vascular imaging devices (Groups II, V, and VII), various surgical procedures (Groups I, III, and VI), and various allelic variant identification processes (Group XI) is because each includes different apparatuses and/or uses different method steps. The distinctness or independence of the presence of absence of modulator(s) (Groups I and III) is because each includes a certain modulator set or lack thereof which are individually unique in structure and function. The distinctness or independence of various vascular diseases (Group II) is because each contains a unique set of characteristics and symptoms. The distinctness or independence of methods involving one or two time points (Group XV) is because each type of method contains a different set of factors with the two-time point method involving relationships

not found in the single time point method. The distinctness of increased versus decreased likelihood disease diagnosis (Group II) is because these diagnosis feature distinctly different goals. The completely separate chemical and entity types of the invention species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The invention Groups I-XV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case polynucleotides of Group X may be utilized in several distinct usages as needed in Group I to identify subjects for therapy, in Group II to identify subjects for further diagnostic evaluation, in Group III to select a therapy, in Group IV to determine benefits of a stent implantation, in Group V to determine benefits in a vascular imaging procedure, in Group VI to determine benefits in a surgical procedure, in Group VII to select a vascular imaging device, in Group VIII to use a computer readable medium and systems to determine predisposition to vascular disease or disorder, in Group IX to select drugs, in Group XI to perform a method and system for identifying allelic variants, in Group XII to provide medical advice, in Group XIII to self assess disease risk, in Group XIV for a health care provider to generate assessment report that may or may not include digital health and digital molecular data in the assessment determination, in Group XV to assess health using both digital molecular and digital health data in its assessment determination, or alternatively in antisense therapy or preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions

for the following reasons: Groups I-IX and XI-XV are directed to processes and methods that recite functionally distinct elements, are not required one for the other, and/or achieve different goals. The inventions of Groupings 1-IX and XI-XV are independent inventions because they are directed to different chemical and entity types regarding the critical limitations therein. For Group I, the goal is identifying subjects for therapy. For Group II, the goal is identifying subjects for further diagnostic evaluation. For Group III, the goal is selecting a therapy. For Group IV, the goal is a stent implantation benefits determination. For Group V, the goal is vascular imaging procedure benefits determination. For Group VI, the goal is surgical procedure benefits determination. For Group VII, the goal is selecting a vascular imaging device. For Group VIII, the goal is a computer readable medium and systems to determine predisposition to vascular disease or disorder. For Group IX, the goal is drug selection. For Group XI, the goal is a method and system for identifying allelic variants. For Group XII, the goal is providing medical advice. For Group XIII, the goal is a self assessing disease risk. For Group XIV, the goal is a health care provider generating assessment report that may or may not include digital health and digital molecular data in the assessment determination. For Group XV, the goal is a health assessment using both digital molecular and digital health data in its assessment determination. The completely separate chemical and entity types of the invention Groups are often separately characterized and published in literature, thus adding to the search burden if all Groups were examined together. Also, processing that may connect two Groups does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences

such as subtractions, additions, and enzymatic action. Thus, the 18 Groups are independent and/or distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 7, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER

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